There's more to learn about ERIVEDGE®
(vismodegib)

Not actual patients.
Images used in this capsule are for illustrative purposes only.

- Erivedge offers **over 8 years of clinical experience**[1]
- Erivedge is the **most prescribed FDA-approved oral treatment** for adult patients with locally advanced or metastatic basal cell carcinoma (BCC)[2]
- **>5,600 healthcare professionals** have prescribed Erivedge[2]*
- **>31,000 patients** have been treated with Erivedge in clinical practice[2†]

*From February 2012-October 2019.
†For the data period January 30, 2012 to December 6, 2019, the number of patients who have been treated with Erivedge in the clinical setting is estimated based on the volume of product sold, as well as assumptions of channel inventory, duration, compliance, and persistence.

Look inside to discover what factors might impact the appropriate treatment choice for advanced BCC

Indication

Erivedge is indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and who are not candidates for radiation.

Boxed Warning

EMBRYO-FETAL TOXICITY

- **Erivedge can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. Erivedge is embryotoxic, fetotoxic, and teratogenic in animals. Teratogenic effects included severe midline defects, missing digits, and other irreversible malformations**
- **Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating Erivedge. Advise pregnant women of the potential risks to a fetus. Advise females of reproductive potential to use effective contraception during and after Erivedge**
- **Advise males of the potential risk of Erivedge exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential**

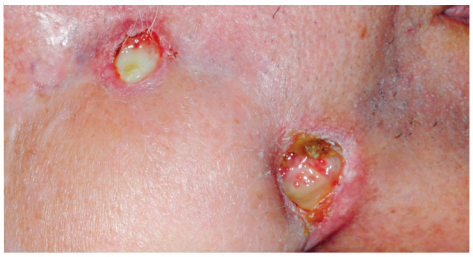
Please see full Prescribing Information, including the **BOXED WARNING** and the Medication Guide, for a complete discussion of the risks associated with Erivedge.

Erivedge® (vismodegib) capsule

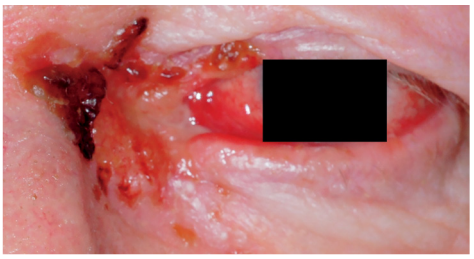
Select Lesion and Patient Factors That May Impact the Appropriate Treatment Choice for Advanced BCC*

What lesion factors might you consider when determining how to treat advanced BCC?[2-4]

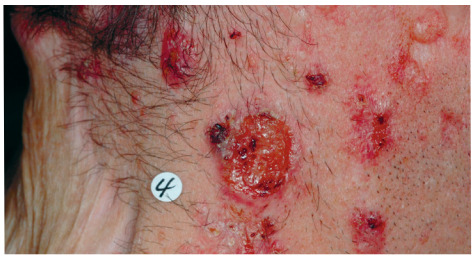
Locally invasive
Tumor extending into underlying tissue, cartilage, bone, or nerve



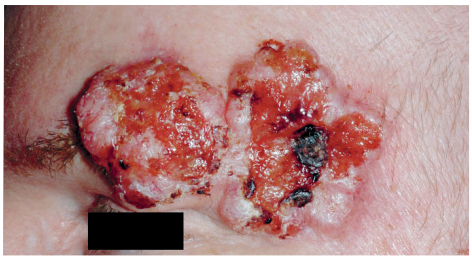
Location of disease
Surgery or radiation would result in significant disfigurement or loss of function



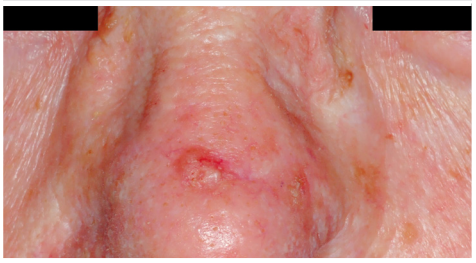
Number of lesions
Surgery would result in significant deformity



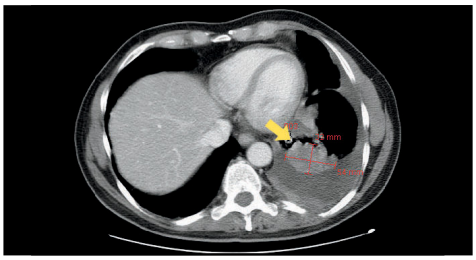
Size
Lesion is large in size



Lesion recurrence
Recurrence in the same location



Metastasis
Metastasis to regional lymph nodes, liver, bone, etc



*All of these patients were ERIVANCE participants.

What patient factors might you consider when determining how to treat advanced BCC?[4-7]

- Comorbidities
- Age
- Concomitant medications
- Patient performance status
- Prior BCC treatment history
- Gorlin syndrome

Assessing lesion and patient factors can help you determine appropriate treatment options for your patients with advanced BCC[4]

EMBRYO-FETAL TOXICITY (cont'd)

- Females of Reproductive Potential: Use contraception during therapy with Erivedge and for 24 months after the final dose

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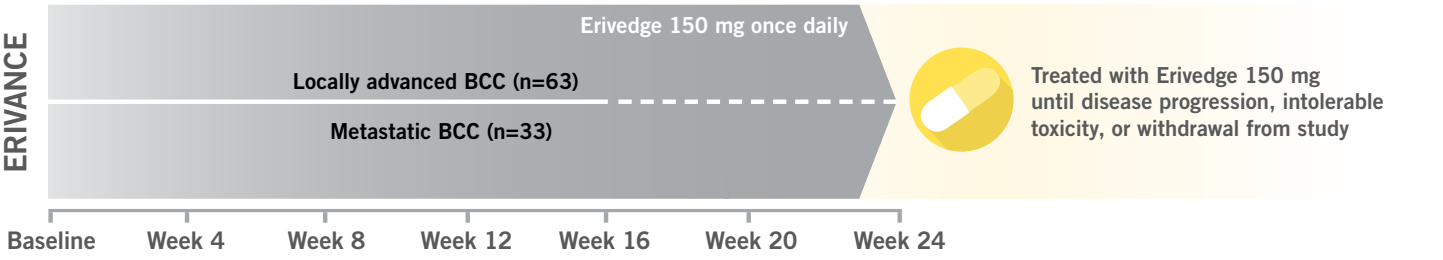
ERIVANCE: The Phase II Pivotal Trial That Demonstrated Clinically Meaningful Benefit in Advanced BCC

Study design[3,8]

Phase II, international, single-arm, 2-cohort, open-label trial

Conducted in 104 patients with either metastatic BCC (n=33) or locally advanced BCC (n=71).
Of the 104 patients enrolled, 96 patients were evaluable for objective response rate (ORR).



- Patients were seen at baseline and every 4 weeks for safety monitoring
- Patients were seen at baseline and every 8 weeks for response assessment

EMBRYO-FETAL TOXICITY (cont'd)

- Males: Use condoms, even after a vasectomy, to avoid potential drug exposure in pregnant partners and female partners of reproductive potential during and for 3 months after the final dose of Erivedge. Do not donate semen during and for 3 months after the final dose of Erivedge
- Blood Donation: Advise patients not to donate blood or blood products while receiving Erivedge and for 24 months after the final dose of Erivedge
- Advise female patients and female partners of male patients to contact their healthcare provider with a known or suspected pregnancy. Report pregnancies to Genentech at (888) 835-2555

Additional Important Safety Information

Severe Cutaneous Adverse Reactions

- Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported during treatment with Erivedge. Permanently discontinue Erivedge in patients with these reactions

Premature Fusion of the Epiphyses

- Premature fusion of the epiphyses has been reported in pediatric patients exposed to Erivedge. In some cases, fusion progressed after drug discontinuation. Erivedge is not indicated for pediatric patients

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Erivedge Reduced Disease Burden Visibly, Histologically, and Radiographically[1-3,8]

In the metastatic BCC cohort, response was assessed according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.0.

Objective response rate (ORR) by independent review from ERIVANCE[3]*

	laBCC (n=63)	mBCC (n=33)
ORR	**43% (n=27)**	**30% (n=10)**
(95% CI)	(30.5-56.0)	(15.6-48.2)
Complete response	21% (n=13)	0% (n=0)
Partial response	22% (n=14)	30% (n=10)
Median duration of response (months)	**7.6**	**7.6**
(95% CI)	(5.7-9.7)	(5.6-NE)

CI=confidence interval; laBCC=locally advanced BCC; mBCC=metastatic BCC; NE=not estimable; SLD=sum of the longest diameter.
*Patients received at least 1 dose of Erivedge with independent pathologist-confirmed diagnosis of BCC. Locally advanced BCC patients were considered responders if they did not experience progression and had ≥30% reduction in lesion size (sum of the longest diameter) from baseline in target lesions by radiography or in externally visible dimensions of target lesions (scar tissue was measured); or had complete resolution of ulceration in all target lesions. Complete response was objective response with no residual BCC on sampling biopsy. Partial response was objective response with presence of residual BCC on sampling biopsy. Complete response was disappearance of all target and nontarget lesions. Partial response was ≥30% decrease in SLD of target lesions from baseline.

Adverse Reactions

- The most common adverse reactions (≥10%) were muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia
- Amenorrhea can occur in females of reproductive potential. Reversibility of amenorrhea is unknown. In clinical trials, 30% of 10 pre-menopausal women developed amenorrhea while receiving Erivedge
- Grade 3 laboratory abnormalities observed in clinical trials were hyponatremia (4%), azotemia (2%), and hypokalemia (1%)
- Additionally, in a post-approval clinical trial conducted in 1232 patients with locally advanced or metastatic BCC treated with Erivedge, a subset of 29 patients had baseline values for blood creatine phosphokinase (CPK) reported. Within the subset of patients, 38% had a shift from baseline, including Grade 3 (3%) increased CPK. Grade 3 or 4 increased CPK occurred in 2.4% of the 453 patients across the entire study population with any CPK measurement
- Adverse reactions identified during post-approval use: drug-induced liver injury, Stevens-Johnson syndrome/toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms

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Erivedge Adverse Reactions: Help Your Patients Know What to Expect

Most common adverse reactions associated with Erivedge[2,8,9]

Incidence of common adverse reactions (≥10%): Pooled analysis of 4 studies (N=138)					
Adverse reactions occurring in ≥10% of advanced BCC patients	Grade 1 (%) (Mild)	Grade 2 (%) (Moderate)	Grade 3 (%) (Severe)	Grade 4 (%) (Disabling or life-threatening)	All grades (%)
Muscle spasms	51.4%	16.7%	3.6%	–	72%
Alopecia	49.3%	14.5%	N/A	N/A	64%
Change in taste (dysgeusia)	34.1%	21.0%	N/A	N/A	55%
Weight loss	25.4%	12.3%	7%	N/A	45%
Fatigue	27.5%	6.5%	5%	0.7%	40%
Nausea	23.9%	5.8%	0.7%	–	30%
Diarrhea	21.7%	6.5%	0.7%	–	29%
Decreased appetite	15.2%	8.0%	2.2%	–	25%
Constipation	17.4%	3.6%	–	–	21%
Arthralgias	11.6%	3.6%	0.7%	–	16%
Vomiting	10.9%	2.9%	–	–	14%
Loss of taste (ageusia)	8.0%	2.9%	N/A	N/A	11%

Adverse reactions reported using *Medical Dictionary for Regulatory Activities* preferred terms and graded using *National Cancer Institute Common Terminology Criteria for Adverse Events v3.0* for assessment of toxicity.
N/A=not applicable, this grade does not exist for this adverse reaction.

- Twenty-nine patients (28%) experienced adverse reactions that led to treatment interruption[2]

Use in Specific Populations
Lactation

- No data are available regarding the presence of vismodegib in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production. Advise women that breastfeeding is not recommended during therapy with Erivedge and for 24 months after the final dose

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

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Learn more about the Erivedge treatment experience[8]

Dosing and administration information

Verify pregnancy status before prescribing Erivedge

Once-daily dosing: 150 mg until disease progression or unacceptable toxicity

- Swallow capsules whole
- **Do not open or crush capsules**
- If a dose is missed, do not take or make up that dose; resume dosing with the next scheduled dose

Median duration of treatment in the ERIVANCE trial was 10.2 months (range, 0.7 to 18.7 months), inclusive of locally advanced BCC and metastatic BCC cohorts

Dose interruption or discontinuation for adverse reactions

Up to 8-week dose interruption for intolerable adverse reactions until improvement or resolution. Treatment interruptions prior to 8 weeks of continuous therapy have not been studied

Permanently discontinue Erivedge if patients experience severe cutaneous adverse reactions, including:

- Stevens-Johnson syndrome
- Toxic epidermal necrolysis
- Drug reaction with eosinophilia and systemic symptoms

Additional features to consider

No fasting required: Erivedge may be taken with or without food

No laboratory monitoring required

No clinically relevant drug-drug interactions expected between Erivedge and:

- Substrates, inducers, or inhibitors of CYP450 enzymes[2]
- Inhibitors of P-glycoprotein
- Gastric pH elevating agents

References: 1. FDA approves Erivedge (vismodegib) capsule, the first medicine for adults with advanced basal cell carcinoma [press release]. San Francisco, CA: Genentech, Inc.; January 30, 2012. **2.** Data on file. Genentech, Inc. **3.** Sekulic A, Migden MR, Oro AE, et al. Efficacy and safety of vismodegib in advanced basal-cell carcinoma. *N Engl J Med*. 2012;366(23):2171-2179. **4.** Lear JT, Corner C, Dziewulski P, et al. Challenges and new horizons in the management of advanced basal cell carcinoma: a UK perspective. *Br J Cancer*. 2014;111(8):1476-1481. **5.** Ibrahim SF. Advanced basal cell carcinoma: treatment overview. *The Dermatologist*. 2014;22(3). http://www.the-dermatologist.com/content/advamced-basa-cell-carcinoma-treatment-overview. Published March 10, 2014. Accessed August 11, 2020. **6.** Levine A, Markowitz O. Update on advanced basal cell carcinoma diagnosis and treatment. *Dermatology Times*. https://www.dermatologytimes.com/skin-cancer/update-advanced-basal-cell-carcinoma-diagnosis-and-treatment. Accessed August 11, 2020. **7.** Amin SP, Russell KJ. Diagnosing, managing aBCC in elderly patients. *Dermatology Times*. https://www.dermatologytimes.com/dermatology-times/news/diagnosing-managing-abcc-elderly-patients. Accessed August 11, 2020. **8.** Erivedge® (vismodegib) capsule Prescribing Information. Genentech, Inc. July 2020. **9.** Common Terminology Criteria for Adverse Events v3.0 (CTCAE). National Cancer Institute. http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf. Accessed August 11, 2020.

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